CHEMICAL SAFETY REPORT

Legal name of applicant(s):	*LUC (UK) Limited*
Submitted by:	*LUC (UK) Limited*
Substance:	*2,2'-dichloro-4,4'-methylenedianiline (MOCA, MbOCA) [CAS 101-14-4; EC 202-918-9]*
Use title:	*Use 1: Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors* *Use 2: Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors.*
Use number:	*1 & 2*

Public version

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LIST OF ABBREVIATIONS

ACH	Air Change Per Hour
ACOP	Approved Code Of Practice
APF	Assigned Protection Factor
ART	Advanced Reach Tool
BLV	Biological Limit Value
BMGV	Biological Monitoring Guidance Value
BRPPA	British Rubber & Polyurethane Products Association
Clocal	Local Concentrations
CMD	Carcinogens And Mutagens Directive
COSHH	Control Of Substances Hazardous To Health
CSR	Chemical Safety Report
ECS	Environmental Contributing Scenario
ERC	Environmental Release Category
ES	Exposure Scenario
EU	European Union
EUSES	European Union System For The Evaluation Of Substances
HSE	Health, Safety And Environment
ISOPA	European Trade Association For Producers Of Diisocyanates And Polyols
LEV	Local Exhaust Ventilation
LoD	Limit Of Detection
MOCA	2,2'-Dichloro-4,4'-Methylenedianiline CAS: 101-14-4
OEL/s	Occupational Exposure Limit/S
OELVs	Occupational Exposure Limit Values
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PROC	Process Category
PU	Polyurethane
RMM	Risk Management Measure
RPE	Respiratory Protective Equipment
SOP	Standard Operating Procedure
TWA	Time Weighted Average
UK	United Kingdom
UK HSE	Health And Safety Executive (UK Government Agency)
WCS	Worker Contributing Scenario
WEL	Workplace Exposure Limit
WWTP	Waste Water Treatment Plant

DECLARATION

The Applicant, LUC (UK) Limited is aware of the fact that evidence might be requested by UK HSE to support information provided in this document.

Also, we request that the information blanked out in the public version of the Chemical Safety Report is not disclosed. We hereby declare that, to the best of our knowledge as of today (24.06.2022) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature: 

Date, Place: 24th June 2022
Cardiff

9. EXPOSURE ASSESSMENT (and related risk characterisation)

This exposure assessment for LUC (UK) Limited (referred to as LUC UK from here on) aims to provide reliable estimates for exposure to workers and to humans via the environment coming from the 2 uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA, MbOCA) at its site in Merthyr Tydfil, United Kingdom, relating to the production of cast polyurethanes (custom-made rollers for end use by the aluminium & steel sectors; and heavy-duty rollers, tensioner pads and spring blocks for end use by the renewable & the offshore energy sector).

A binding occupational exposure limit value of 10 µg/m^3 for MOCA was included in Annex III to the Carcinogens and Mutagens Directive (CMD) (Directive 2004/37/EC) - carcinogens or mutagens at work on 5 June 2019. According to the text of the amendment,[1] Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 11 July 2021. This means that all sites using MOCA compounds across the EEA must comply with this value or their national occupational exposure limit value if it is lower. The national value in the UK is lower 5 µg/m^3 and this is the value that is relevant for this exposure assessment. There is a skin notation for both values indicating that the dermal route is the main route of exposure. The UK HSE have introduced Biological Monitoring Guidance Values (BMGVs) into their Guidance Note EH40 - 'Occupational Exposure Limits'[2] for MOCA. The value is 15 µmol MbOCA/mol creatinine in a urine sample collected from occupationally exposed workers.

LUC UK has technical and organisational measures in place to minimise worker exposure to MOCA at its site. It has occupational exposure monitoring programs in place (both personal air monitoring and biological monitoring) and all measured values to date are well below the limit values.

LUC Group is a downstream user of MOCA in the supply chain of Suzhou Xiangyuan New Materials Co., Ltd. (Suzhou) and their use of MOCA is currently covered by the application submitted by REACHLaw acting as only representative for Suzhou under Brexit transitional arrangements, as the Commission has not yet taken a decision on the application. It submitted a downstream user application to cover use at 4 sites in the EEA on 20.05.2020 and the ECHA opinion on this application was issued to the Commission for decision making on 28.07.2021. Details of the application are available on the ECHA website.[3] As this application was submitted before the end of the Brexit transition period, it included also use at the UK site. Since the 01.01.2021, the UK site is now under UK REACH and the application submitted under EU REACH is not relevant. LUC UK is submitting this application to cover use at the UK site.

Table 1. Binding occupational exposure limit values for MOCA[4]

	Limit value –8 h TWA (mg/m^3)
European Union	0.01[1]
UK	0.005[1]
1. Skin	

[1] DIRECTIVE (EU) 2019/130 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0130&from=EN

[2] https://www.hsl.gov.uk/online-ordering/analytical-services-and-assays/biological-monitoring/bm-guidance-values

[3] LUC application for authorisation for 2 uses of MOCA under EU REACH; use 1 ECHA ID 0225-01 and Use 2 ECHA ID 0225-02 available on the ECHA website at https://echa.europa.eu/applications-for-authorisation-previous-consultations

[4] Values are taken from GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs) database available at https://limitvalue.ifa.dguv.de/

9.1 Introduction

9.1.1. Overview of uses and Exposure Scenarios

The average annual tonnage used at the site for 2019-2021 was 2.1 tonnes MOCA. Release rate estimates are based on emissions data and based on the tonnage used for the same year. The highest forecasted annual tonnage that may be used over the duration of the 12-year review period requested is the 3.8 tonnes taken forward in the assessment to assess the worst-case situation.

Ca. 68 % and 32 % of the tonnage is used for Use 1 and Use 2 respectively.

The majority of the polyurethane production is done using casting machines fitted with MOCA Feeding Unit (glovebox + melter) for the loading of MOCA. A small proportion [0-20 %] [redacted] is done by semi-automated casting when it is not possible to use the machines. Separate worker contributing scenarios are given for the loading and mixing steps for the automated and semi-automated processes. The casting and curing steps are the same for both processes.

Table 2 lists the exposure scenario (ES) assessed in this CSR.

Table 2. Overview of exposure scenarios

Identifiers*)	Market Sector	Titles of exposure scenarios	Tonnage (tonnes per year)
ES 1: IW-1	Industrial end use at site	Use 1 Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors Use 2 Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors.	3.8 tons Use 1: 2.58 Use 2: 1.22

The environmental contributing scenario and worker contributing scenarios are summarised in Table 3.

Table 3. Overview of Contributing Scenarios

Contributing scenario	ERC / PROC	Name of the contributing scenario	Size of the exposed population
ES 1:			
ECS1	ERC 6a	Industrial use of MOCA in the manufacture of hot cast polyurethanes	Regional: 20M Local: 10k
WCS 1	PROC 1	Delivery and storage of MOCA	
WCS 2	PROC 8b	Transfer of MOCA to MOCA Feeding Unit (glovebox & melter)	
WCS 3	PROC 1	Automated process	
WCS 4	PROC 5	Semi-automated process	
WCS 5	PROC 4	Transferring liquid polyurethane to moulds	
WCS 6	PROC 28	Maintenance & cleaning	
WCS 7	PROC 8b	Waste management	

9.1.2. Introduction to the assessment

This Chemical Safety Report (CSR) and related exposure scenario has been prepared to support LUC UK's application for authorisation for the continued use of MOCA in the production of cast polyurethanes for end-use in the steel and aluminium sectors and the offshore and renewable energy sectors at its site in Merthyr Tydfil, United Kingdom.

An entry for MOCA was included on Annex XIV of the REACH Regulation due to its intrinsic properties as a carcinogen (Carc.1B). As per Art 62(4)(d), an application for authorisation solely needs to consider those potential risks coming from the intrinsic properties given in the entry. Lung cancer due to the dermal route of exposure is the dominant health impact coming from its classification as a carcinogen. Accordingly, this CSR only considers potential human health impacts and does not consider potential environmental impacts. However, as humans may be exposed via the environment, this is considered in the assessment.

9.1.2.1. Environment

As outlined above, potential risks to the environment are not considered in the CSR.

9.1.2.2. Humans via the Environment

Humans may be potentially exposed to MOCA via the environment due to air emissions from the site. An assessment of the oral exposure via the food chain and inhalation exposure to local and regional populations has been performed in this CSR. As LUC UK has measures in place to prevent and minimise release of MOCA to the environment, releases to air are very low and negligible for wastewater and soil. These measures are described in the next sections.

Releases to wastewater

Releases to soil and water at the site are prevented by prohibiting the washing of empty containers, glassware, reaction vessels, etc. and applying spill protocols to ensure that MOCA does not enter the drains. MOCA is stored in dedicated storage facilities in sealed drums (see location on the site schematic given in Figure 1). All solid materials that have been in contact with MOCA are collected for incineration. The waste stream codes are given in Table 4.

Table 4. EWC codes for MOCA waste streams

Description of waste stream	Waste stream codes
Empty MOCA inlay bags	EWC code 15 01 10*
Contaminated Personal Protection Equipment (PPE) and other solid materials that were in contact with the substance	EWC code 15 02 02*
Equipment cleaning and other maintenance activities	EWC code 15 02 02*
MOCA waste from production line	EWC code 16 03 05*

Figure 1. Plant schematic showing the production area and the chemical storage area

LUC UK therefore has measures in place to ensure that releases of MOCA to the aquatic compartment are minimal.

Releases to air

The potential for MOCA release to workplace air is minimised by the use of a glovebox for machine loading and LEV points for the semi-automated process. LUC UK is currently installing filters in the exhaust ventilation system to remove particulates from the exhaust air. Air releases of MOCA are expected to be very low because of the very low vapour pressure of molten MOCA and low dustiness of the MOCA pellets.

Releases to soil

There are no releases to soil due to the technical and organisational measures in place at the site.

Table 5. Environmental RMMs at the LUC UK site

Compartment	RMM	Stated effectiveness
Air	LEV filters being put in place	Not measured
Water	Process has no contact with water, no washing of empty containers etc. Spill protocols are in place	100 %
Soil	Incineration of all contaminated materials.	100 %

Scope and type of assessment:

Exposure to MOCA via the environment causes cancer via the inhalation route and the oral route. All airborne MOCA particles are assumed to be respirable and oral exposure to non-respirable particles is not considered. The additional risk of cancer via oral exposure via the food chain (drinking water and fish) is assessed quantitatively.

The scope and type of assessment is summarised in Table 6.

Table 6. Type of risk characterisation required for human via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion RAC/32/2015/10 rev 1
Inhalation: Long Term	Quantitative	ELR = 5.43E-05 per µg/m3 MOCA for 70 yrs
Oral: Long Term	For inhalation of particles: not needed. Assume all inhaled material is respirable (worst case) For food chain: quantitative	ELR = 9.43E-05 per µg/kg bw/day for 70 yrs

9.1.2.3. Workers

The Exposure Scenario give the operating conditions (OCs) and risk management measures (RMMs) in place at the LUC UK site to minimize exposure.

The following risk management measures are in place

- [65-100 %] [redacted] of production is automated
- A glovebox is used for MOCA transfer from the inlay bags to the feeder
- Access to the storage areas is restricted to authorized personnel
- Standard operating procedures are in place and all workers receive regular training on how to work safely with chemicals, which PPE and RPE to use and how to fit it properly
- Work practices are in place to limit potential worker exposure is limited to the lowest possible level

The locations of the LEV units and extraction points are shown in the site plan given in Figure 2. The exhaust ventilation is a centrifugal type with a fan speed of 280-3464 RPM and an inlet pressure of -1380 Pa. Filters are being installed in the system to remove particulates from the exhaust air before release (see Appendix II). Due to the addition of the filter unit, the capacity of the LEV will be increased to 6500 m^3/h.

Figure 2. LEV units and extraction points at the site

The site has one 8h shift per day and is operational 5 days a week. There are 13 employees at the site and 4 operators have tasks that may have potential to MOCA exposure. As will be outlined in the next chapters, the groups potentially exposed were defined based on the tasks done. Group 1 refers to the 4 LUC UK operators that work on the production process and Group 2 refers to the contractors from an external service provider who do specialised maintenance tasks.

The work practices are in line with those described in the joint UK HSE and British Rubber & Polyurethane Productions association[5] on how to work safely with MOCA. The instructions for workers available on the UK HSE website are also followed[6]. Operators are trained on the UK HSE guidance on the use of gloves for working with MOCA and the poster is on the walls at the site.[7] All RPE and PPE worn by the operators are used as per the manufacturers' instructions and all operators are trained on their correct use. The choice of PPE and RPE depends on the task undertaken. An overview of the PPE and RPE used is given in Table 7. Table 8 summarizes the PPE and RPE used for all worker contributing scenarios.

The locations of changing areas (lockers and shower facilities) and PPE/RPE storage are shown in the site schematic given in Figure 1. RPE is maintained regularly, and employees check their equipment before each use. A fit check for the seal is part of the training for operators using RPE at the site (see Appendix III).

[5] 2014 BE SAFE WITH MbOCA leaflet prepared by the UK HSE and BRPPA available at https://brppa.co.uk/wp-content/uploads/2014/03/BRPPA-HSE-Safe-Use-Of-MbOCA.pdf

[6] UK HSE Guidance for preventing skin contact during the removal of gloves available at the UK HSE website at https://www.hse.gov.uk/pubns/msa21.htm

[7] https://www.hse.gov.uk/skin/posters/glovesreuse.pdf

Table 7. Photos of operators wearing PPE specific for the tasks covered by tasks described in WCSs 1-7

	Type of PPE	Conforming to the following standards	Photo	Relevant for
Footwear	Safety shoes	EMMA ROY D S2 – EN 20345 EMMA RINGO D S2 – EN 20345 EMMA ANDES XD S3 – EN 20345		1-7
Eye and face protection	Safety glasses	LDPE Prime Optix Rox 55-18 Cristal – EN 166 F CE		1-7
Gloves	Nitrile	SHOWA Nitrile 7585 – EN 374		2-7
	Latex	MSAFE LATEX MODEL 4140 Powdered – EN 455, EN-ISO 374-5:2016, EN-ISO 374-1:2016+A1:2018/Type C Gloves glove box MOCA feeder – Natural Black Rubber Latex thickness 0.76-1.01mm Length 30" Port size 10" (±1")	 	2

	Technical (no chemical protection)	Work/cutting resistant gloves: OPTI Flex 0838 Comfort Cut – EN 388	   	1, 2 ,6*, 7*
		Heat resistant gloves: Ansell Crusader Flex – EN 388 and EN 407	  	4, 5
Protective clothing	Disposable Apron	CMT PE Apron : PE embossed 800x1250x0.02mm – EN 1186		2, 4, 5, 6

	Coveralls (eg. Tyvek suit)	Thor Coverall Type 5,6 – Protective clothing Category III EN 13034:2005+A1:2010 EN ISO 13982-1:2004+A1:2010 EN 1073-3:2002 EN 14126:2003+AC:2004 EN1149-5:2008 EN ISO 13688:2013		6*
	Disposable sleeves	CMT Sleeve Covers: PE embossed 400x200x0.02mm – EN 1186		2, 4, 5, 6
	Work clothes	Trousers: Planam OEKO-TEX Standard 100 (65% polyester, 35% cotton) – EN 14404 type 2 Longsleeves: Santino (60% cotton, 40% polyester) 210g/m^3 – no standard Jacket: OEKO-TEX Standard 100 (65% polyester, 35% cotton) – no standard	   	1-7

Respiratory protection	Mask: half Face mask 3M 7500 series	EN 140	 	2, 4, 5, 6, 7
	Filters Gas- and vapour filter; 3M 6057 Dust filter ; 3M 5935	ABE1 – EN 14387 P3 R – EN 143	   	
	Mask: Full face mask: 3M 6000 series	EN 136	 	6*
	Filters: Gas- and vapour filter; 3M 6057 ABE1 Dust filter ; 3M 5935 P3 R	EN 14387 EN 143	See pictures at half face respiratory mask	

* Some tasks

Table 8. Summary overview of PPE for the tasks covered by WCS 1-7

			Eye protection	Gloves				PPE				Footwear	RPE	
number	Title	what this covers	Glasses	Chemical resistant	Glove box gloves	Cut resistance gloves (no chemical protection)	Heat resistant	Work clothing	Disposable apron	Coveralls (e.g. Tyrvek)	Disposable sleeves	S3 shoes	Half face mask + ABE1 P3 filter	Full face mask + ABE1 P3 filter
WCS 1	Delivery and storage of MOCA	Tasks involving taking delivery of MOCA in drums on pallets and transferring to storage area	x			x		x				x		
WCS 2	Transfer of MOCA to MOCA Feeding Unit (glovebox & melter)	Loading the drum to the glovebox, opening the inlay bag inside the glovebox and tipping the contents onto a hopper	x	x	x (+ under gloves)	x		x	x		x	x	x	
WCS 4	Semi-automated process	Dispensing melted MOCA from the machine to a reaction vessel and mixing with the pre-polymer reactant	x	x			x	x	x		x	x	x	
WCS 5	Transferring liquid polyurethane to moulds	Dispensing the liquid polyurethane to moulds	x	x			x	x	x		x	x	x	
WCS 6	Maintenance & cleaning	Any task where there is potential for exposure to MOCA	x	x		x*		x	x	x*	x	x	x	x*
WCS 7	Waste management	Any task involving MOCA waste streams	x	x		x*		x				x	x	

*dependent on the task

Training is organised in compliance with the code of good practiec to COSHH.[8] The pre-polymer reactants contain diisocyanates and the training requirement as per the restriction given in entry 74 of Annex XVII of the REACH Regulation[9] will further enhance existing training programs and will reinforce worker compliance on personal protective equipment (PPE) and respiratory protective equipment (RPE) usage. The site is working with ISOPA[10] to organise the trainings in late 2022. As MOCA has a workplace exposure limit value (WEL), LUC UK monitors worker exposure to ensure it is controlled and as low as reasonably practicable. MOCA also has a biological guidance value and LUC UK has biomonitoring programs in place.
Biomonitoring campaigns are done every year on a LUC Group level and occupation air measurements every 3 years since 2016. Exposure values are very low. All personal air measurements performed show low concentrations of MOCA in the air (all below the limit of detection (<1 µg) and less than 1% of the WEL).

Scope and type of assessment:

The scope of the exposure assessment and the type of risk characterization required for workers are given in Table 9. The exposure estimates (ART 1.5 for inhalation exposure and Riskofderm for dermal exposure) or measured values refer to the exposure of workers to MOCA and are expressed as an 8-hour Time Weighted Average (TWA) to represent a standard working day of an employee. Biomonitoring data where the MOCA content of urine samples collected at the end of shift at the end of the working week was determined was used to determine combined exposure from all routes.

Table 9. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion from RAC/32/2015/10 rev 1
Inhalation	Systemic Long Term	Quantitative	*ELR = 9.65E-06 per µg/m³ for 40 years*
Dermal	Systemic Long Term	Quantitative	*ELR = 3.38E-05 per µg/kg bw/day for 40 years*
Combined	Systemic Long Term	Quantitative	*5 µmol/mol creatinine in a Friday afternoon sample (corresponding to a daily dose of 17 µg) corresponds to ELR of 16.4E-06*

[8] Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply; Available at https://www.hse.gov.uk/pubns/priced/l5.pdf
[9] COMMISSION REGULATION (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2020.252.01.0024.01.ENG
[10] https://www.isopa.org/

9.2. Exposure scenario 1: Industrial use of MOCA in the manufacture of polyurethanes

Market sector: Use at industrial site

Sector of use: 0 other

Article categories: PC 32: Polymer Preparations and Compounds

Environment contributing scenario(s): Industrial use of MOCA in the manufacture of polyurethanes (ERC 6a)

Worker contributing scenario(s):

WCS 1: Delivery and storage of MOCA (PROC 1)

WCS 2: Transfer of MOCA to MOCA Feeding Unit (glovebox & melter) (PROC 8b)

WCS 3: Automated process (PROC 1)

WCS 4: Semi-automated process (PROC 5)

WCS 5: Transferring liquid polyurethane to moulds (PROC 4)

WCS 6: Maintenance & cleaning (PROC 28)

WCS 7: Waste management (PROC 8b)

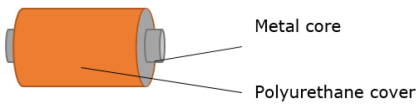
Subsequent service life exposure scenario(s): none

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): none

Description of the activities and technical processes covered in the exposure scenario:

LUC UK uses MOCA as an amine curative/chain extender in the manufacture of polyurethanes. The polyurethanes are casted in moulds and after curing and post-curing are used as components (heavy-duty rollers, tensioner pads and spring blocks) of larger systems used in the steel and aluminium sector and off-shore and renewable energy sectors. Examples of the polyurethane components are given in Figure 3.

Use 1 & Use 2



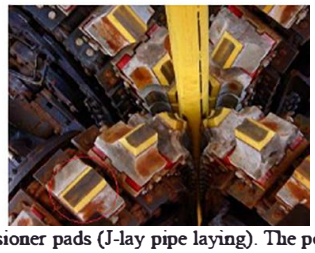
Schematic of a polyurethane covered roller

Use 1 Set of 4 bridle rollers in a steel processing line

Use 2 Example of heavy duty rollers ready for shipping. The dark coloured layer is the polyurethane. The steel roller body is in red.

Use 2

Schematic of tensioner pad



Tensioner pads (J-lay pipe laying). The polyurethane layer is yellow.

Use 2	
 Schematic of a block	 Spring block

Figure 3. Examples of the polyurethanes covered by Use 1 and Use 2

Polyurethane manufacture where MOCA is used as the chain extender reactant in the synthesis is done primarily in an automated process using a MOCA Feeding Unit (glove box + melter) to load MOCA to the casting machine and where all the reaction steps are done by the machine. The liquid polyurethane is dispensed from the machine to heated moulds where it cools and cures to take the shape of the mould. The filled mould is moved to an oven for curing and post-curing steps. The MOCA content of the cured polyurethane is << 0.1 % (w/w) due to the stoichiometry of the reactants used in the synthesis. The steps are given in Figure 4. Less than [0-20 %] [redacted] of manufacture is done in a semi-automated process where reaction steps are not done by the machine. In this case, melted MOCA is dispensed from the storage unit in the machine [redacted] MOCA reacts with the other reactants under stirring. The obtained liquid polyurethane is then poured to the preheated moulds, followed by the curing and post-curing steps, which are the same as for the automated process. As both automated and semi-automated processes are in the same area and the same operators may do tasks related to both, one exposure scenario is presented that covers both production processes.

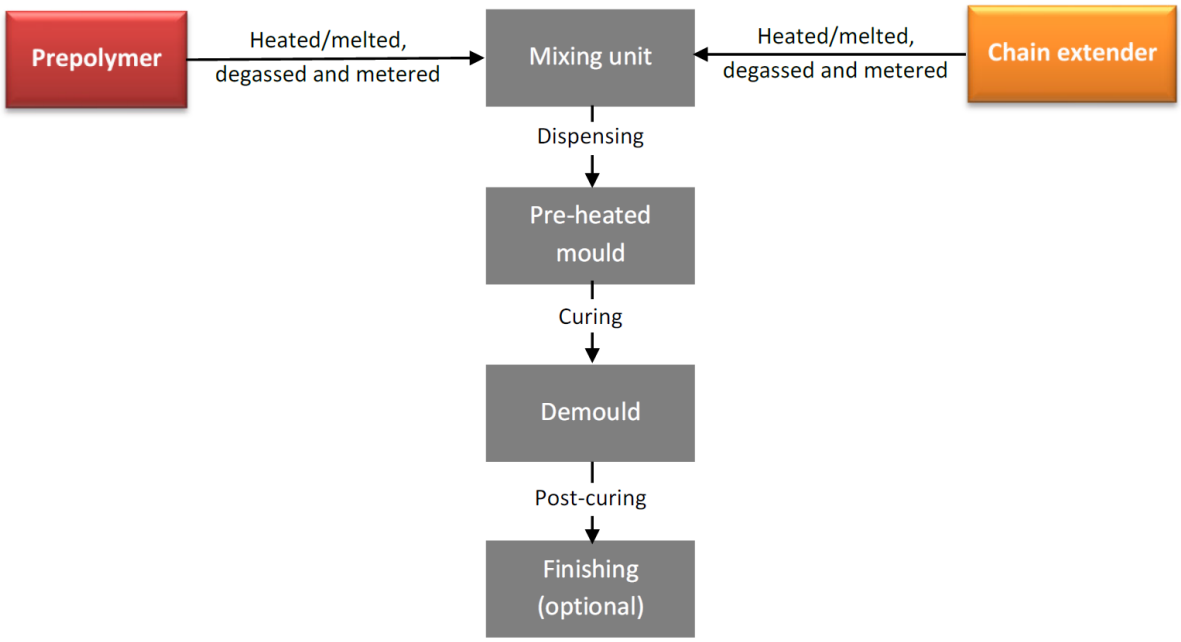


Figure 4. The basic steps for cast polyurethane manufacture

Explanation on the approach taken for the ES:

Considering the low vapour pressure of MOCA and the high skin permeation, biomonitoring is used to assess occupational exposure as recommended per ECHA risk Assessment Committee. Therefore, data from biomonitoring campaigns has been used to quantify the risk as outlined in Chapter 9.0 monitoring campaigns.

Summaries of recent workplace personal and biomonitoring exposure monitoring at the LUC UK site are given below.

Personal measurements

Personal monitoring campaigns are performed regularly by accredited external service providers according to standard methods (OSH 71). Values from recent campaigns are summarised in Table 10. All values were below the limit of detection of the analysis method (1 µg/m^3) and the TWA value was obtained by dividing the LoD value by the sample volume. The full details are given in Appendix I. The sampling time was shorter than 8 hours and in the next campaign the site will do sampling for 8h. If the additional measurement shows that the air occupational levels are negligible, the site will stop measuring until a process change in implemented. Otherwise, the site will continue monitoring and

review the operating conditions and risk management measures to bring the values down to the negligible level.

Table 10. Summary of personal air monitoring data 2016-2020

Monitoring period covered the operator doing the following tasks	Year and sample number	8 h TWA value µg/m^3
Normal range of duties for an operator during an 8h period	2016 2017 2020	< 2.5* < 4* < 3*

* measured value below limit of detection (LoD) of the analysis method used (1 µg/m^3), the TWA value was estimated by dividing the LoD by the sample volume

Biomonitoring program

Biomonitoring campaigns are performed yearly at a LUC Group level. Urine samples are collected from the operators at the end of shift typically on Thursdays and sent for analysis at an accredited external laboratory. The values are compared with the UK Biological Monitoring Guidance Values (BMGVs) guideline value of 15 µmol MOCA/mol creatinine. Data from the 2020 campaign are summarised in Table 11. All values obtained are all operators were below the limit of detection of the method used (LOD = 0.42 µmol/mmol creatinine). The values indicate that exposure is low and at the level that is used as a reference for a non-exposed population. Data from earlier campaigns are given in Appendix 1.

Table 11. Biomonitoring data from the 2020 campaign

Year	Day sample taken	Number of workers from whom urine samples were collected	Number working with MOCA	Limit of detection (LoD) of the analysis method used (µmol MOCA/mol creatinine)	Number of samples with values < LoD
5.3.2020	Thursday end of shift	8	4	0.42	8

The detailed exposure scenario was developed based on details of the conditions under which each activity is carried out and the duration and frequency of each task. The frequency of a specific activity in the worker contributing scenarios is expressed as daily activity unless otherwise stated.

As outlined in Chapter 9.1, LUC UK has measures in place to minimise release to the environment. Releases to soil and water at LUC UK's site is prevented by prohibiting the washing of empty containers, glassware, reaction vessels, etc. and applying spill protocols to ensure that MOCA does not enter the drains. All solid materials that have been in contact with MOCA are collected for disposal by licenced waste providers. Exposure to humans via environmental releases is based on monitoring data using applicable models (EUSES) and guidance.

9.2.1. ECS 1: Industrial use of MOCA in the manufacture of hot cast polyurethanes

Emission to water

No release to wastewater. The release fraction used for modelling was estimated as 0.0 % (see Table 12).

Emission to air

Air releases of MOCA are expected to be very low because of the very low vapour pressure of molten MOCA and low dustiness of the MOCA pellets. To cover the possible air emissions, an air emission factor for liquid curing agents from OECD Emission Scenarios for Plastic Additives (2009) for compounding activity was used in the calculations. The air emission factor for solid curing agent was reported as 0 % indicating no releases to air, but because the substance is used in liquid form during some process steps, air emission factor for a liquid curing agent (Fcompounding, air = 0.005 %) was used as a worst case scenario

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: ≤ 1.58E-02 tonnes/day
• Annual use amount at site: ≤ 3.8 tonnes/year
Technical and organisational conditions and measures
• Air abatement: filters will be installed (see details in Appendix II)
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0 %] No release to wastewater
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (no waste) *No waste generated.*
Other conditions affecting environmental exposure
• General good practice: Trained staff, protocols for chemical spills • No water used in process or maintenance (cleaning) operations

9.2.1.2. Releases

The MOCA tonnage per year used in the assessment is 3.8 tons. This value comes from the predicted maximum tonnage use during the requested review period. The release factors used in the assessment are given in Table 12.

Table 12. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor after on site RMM:** 0 %
Air	Estimated release factor	**Release factor after on site RMM:** 0.005 % **Local release rate:** 7.92E-04 kg/day
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0 %

9.2.1.3. Exposure and risks for the environment and human via the environment

The predicted environmental concentration in the atmospheric compartment (PEC_{air}) for both local and regional scales were estimated using EUSES. The daily use amount was calculated according to 240 working days. For waste treatment operations input parameters, "No (no waste)" was chosen as there is no release of waste to the environment. The other parameters are default EUSES values.

Table 13. Exposure concentrations for the environment – on local and regional scales

Protection target	Local scale	Regional scale
Air	**Local PEC:** 1.46E-07	**Regional PEC**: 8.96E-12
Man via environment - Inhalation (systemic effects)	**Concentration in air:** 1.46E-07	**Concentration in air:** 8.96E-12

Table 13 gives the local and regional PEC values estimated with EUSES. The local PEC value was used as the worst-case estimate of $Clocal_{air}$= 1,46E-07. This value was used for the risk characterisation for humans via the environment.

Table 14. Contribution to oral intake for humans via the environment from local and regional contributions

	Daily dose (local)	Daily dose (regional)
Daily intake via food	1.63E-07 mg/kg bw/day	2.72E-11mg/kg bw/day

Table 14 gives the estimated daily doses of MOCA from food consumption for local and regional populations from air-emission values.

Conclusion on risk characterisation:

Using the dose response values given in Table 6, the excess lifetime cancer risk values for lung cancer for local and regional populations can be estimated. The values are given in Table 15.

Table 15. Individual excess life cancer risk values of lung cancer for local and regional populations

Individual Excess Lifetime Cancer risk	Local	Regional
Individual Excess risk of lung cancer for general population 70 years (inhalation)	7.87E-09	4.89E-13
Individual Excess risk of lung cancer for general population over 70 years (oral)	1.54E-08	2.57E-12

9.2.2. WCS 1: Delivery and storage of MOCA (PROC 1)

Drums are received via internal transport between the LUC UK and LUC Belgian sites. The number of drums per delivery varies between 12-24 drums at a time. The drums are transported in the original packaging of the manufacturer. Drums are always placed on a pallet which will be sealed to make sure the drums are not displaced during transport.

The drums are stored in a locked storage area. The maximum number of drums stored on site at any time is 30 drums. The sealed drums are not opened in the storage area and are taken to the machine for loading as needed. The drum ring and lid are removed only when the drum is next to the machine. The inlay bag containing MOCA granules remains closed and is only opened inside the glovebox. There is no potential for exposure during delivery and storage.

1 operator typically takes delivery and moves the sealed drums to the storage area and from the area to the machines. The operator wears work clothing, safety shoes, safety glasses and cut resistant gloves doing these tasks. The task takes ca. 15 mins and is done 2-3 times per year.

Figure 5. Photos of the chemical storage areas

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	Qualitative
• Substance as such. Concentration of MOCA: 100 %	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: 15 mins	
• Frequency: 2-3 times per year	
Technical and organisational conditions and measures	
• Containment: Closed system (minimal contact during routine operations)	
Room ventilation: basis general ventilation (1-3 ACH)	
• Local exhaust ventilation: No	
• Occupational Health and Safety Management System: Advanced*	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No	
• Face/eye protection: Yes	
Other conditions affecting workers exposure	
• Place of use: Separate storage room outside the building	
• Process temperature: Room temperature	
* LUK UK's OSH management system can be considered as "advanced" as all activities are undertaken with appropriate and well maintained equipment by trained personnel operating under supervision; Ensure regular inspection, cleaning and maintenance of equipment and machines; Clear spills immediately and dispose of waste safely; Ensure daily cleaning of the equipment[11]	

[11] Harmonised value as given in the ENES report "*Mapping of the Conditions of use (input parameters) of the different tools for workers assessment*" December 2020 available at https://echa.europa.eu/documents/10162/22786913/harmnised_conditions_of+use_for_workers_en.pdf/3b327551-19b3-5d56-8b13-a608695d4419

9.2.2.2. Exposure and risks for workers

Conclusion on risk characterisation:

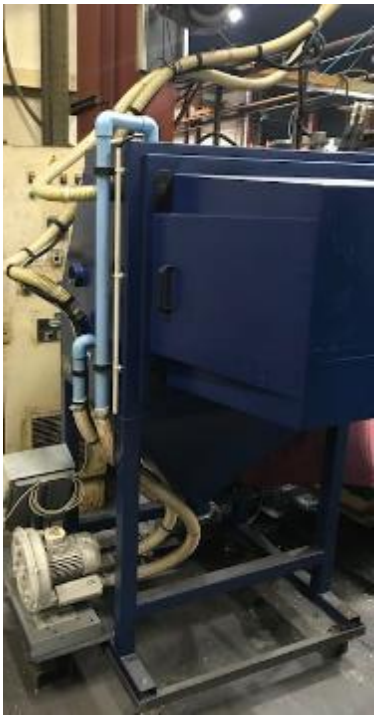
There is no potential for exposure. The qualitatively determined exposure estimate of 0 µg MOCA/m³ is used as the basis for risk characterisation.

9.2.3. WCS 2: Transfer of MOCA to MOCA Feeding Unit (glovebox & melter) (PROC 8b)

This activity covers the transfer to MOCA from the drums to the MOCA feeding unit in the casting machine via the glovebox.

The operator unseals the drum and removes the ring and lid. The inlay bag containing MOCA is not opened. The operator positions the drum on the rear side of the glovebox (see Figure 6a) and closes the glovebox (see Figure 6b). Once the glovebox is closed, the operator uses gloves of the glove box to open the inlay bag and the MOCA granules flow from the bag into the funnel of the MOCA feeder (see Figure 6c). MOCA granules are then automatically fed through a closed system to a built-in melting unit (MOCA melter) and subsequently to the storage tank, where the liquid chain extender is dewatered (see Figure 6d, the blue chamber). The rest of the process steps for melting, dosing and reacting with the pre-polymer are fully automated and require no manual intervention (see WCS 3). There is a waste bag on the side of the glovebox for the empty inlay bag. This bag is sealed airtight and will be replaced regularly (during this task the LEV is positioned above the opening of the glovebox and the operator wears the PPE as mentioned in the WCS). The waste bag will be removed, sealed and disposed of in the waste stream: 15 01 10*.

One operator does the transfer task. Positioning the drum in the glovebox and using the glovebox to open the inlay bag takes about 1 minute and is done typically ca. once a week. 2 operators share the task meaning that they each spent ca. 1 min every 2 weeks doing this task. The operators wear work clothing, safety shoes and glasses, a half mask RPE with a ABE1 P3 filter, nitrile gloves and disposable sleeves and an apron for handling the drum and handling the empty inlay bag. There is a LEV point where the open drum is positioned in the glovebox.



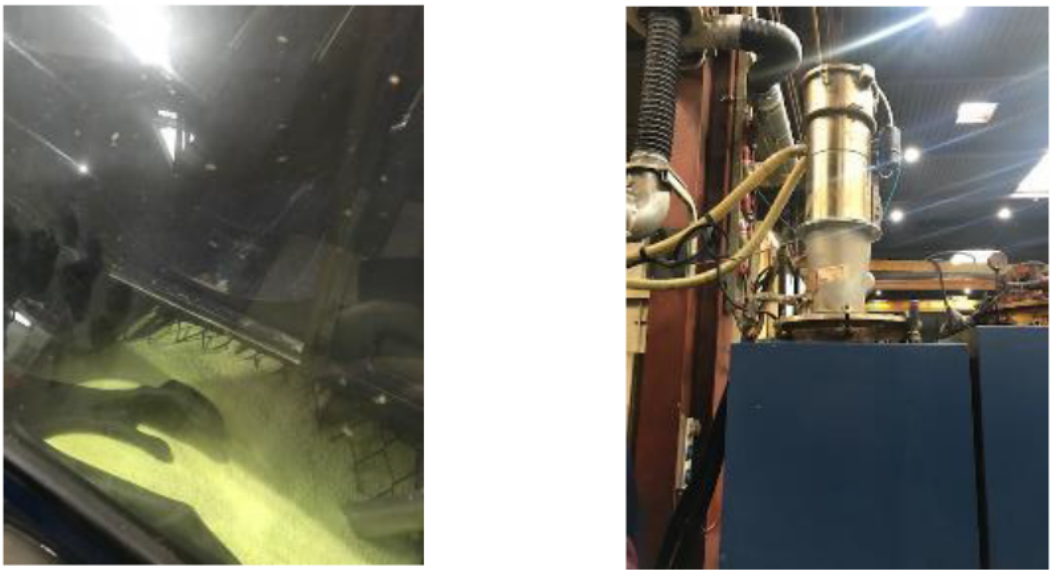


Figure 6. Photos showing (a) an operator positioning MOCA drum on MOCA feeder, the closed door at the rear of the glovebox, (c) using the gloves to open the inlay bag and (d) and MOCA storage unit in the casting machine

9.2.3.1. Conditions of use

Inhalation	Method
Substance emission potential	ART 1.5
• Substance product type: powders, granules or pelletised materials	
• Dustiness: granules, flakes or pellets	
• Moisture content: Dry product (< 5 % moisture content)	
• Powder weight fraction MOCA: 1	
Activity emission potential	
• Duration of activity & frequency: 1 min every 2 weeks	
• Activity class: Transfer of powders, granules or pelletised material	
• Situation: Falling of powders, granules or pelletized materials	
• Level of agitation: Transferring 10 -100 kg/min	
• Type of handling: Careful transfer involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner e.g. careful weighing in laboratory	
• Drop height: < 0.5 m	
• Containment level: Handling that reduces contact between product and adjacent air	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	
Dispersion	
• Work area: Indoors	
• Room size: > 3000 m³	
Technical and organisational conditions and measures	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
• Primary: Low specification glovebox (efficiency 99.9 %) ART model default: Glovebox with one chamber	
• Secondary: No localized controls (0.0 % reduction)	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Occupational Health and Safety Management System: Advanced	
• Face/eye protection: Yes	

• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Dermal	Method
Filling, mixing or loading	Riskofderm
Quality of the ventilation: Normal or good ventilation	
Frequency of skin contact with the contaminant occurs: Rare contact	
Kind of skin contact with the contaminant occurs: Light contact	
Product type: Low or moderately dusty solid	
Significant aerosol or splashes formation: No	
Level of automation: Manual task	
Rate of use: 100 kg/min	
Percentile: 75th	
Cumulative duration of the scenario during a shift: 1 minute every 2 weeks	
Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Glovebox with efficiency of 99.9 % - Gloves with dermal effectiveness of 95 % - Frequency (1 min every two weeks)	

9.2.3.2. Exposure and risks for workers

The measured and modelled exposure concentrations are reported in Table 16.

Table 16. Exposure concentrations for WCS 2

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (8h TWA, µg/m^3)	Exposure value corrected for PPE* (µg/m^3)	Exposure value corrected for PPE and frequency** (µg/m^3)
WCS 2	Inhalation	ART 1.5	3.40E-03	1.70E-04	1.70E-05

*1/20 **1/20

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (µg/70 kg bw/day)	Exposure value corrected for gloves* (µg/70 kg bw/day)	Exposure value corrected for other factors** (µg/70 kg bw/day)
WCS 2	Dermal	Riskoderm	111.14	5.56	5.6E-04

*1/10 **1/10 (Frequency) **1/1000 (Glovebox)

Conclusion on risk characterisation:

The modelled exposure values from the inhalation and dermal routes were 1.70E-05 µg/m^3 and 5.6E-04 µg/kg bw/day respectively giving excess lifetime risk values of 1.64E-10 and 1.878E-08 respectively. This gives a combined excess lifetime cancer risk 1.89E-08. As noted in the Chapter 9.0, biomonitoring data was used as the basis for risk characterisation as it covers all routes of exposure. The risk characterisation from biomonitoring data is summarised in Chapter 9.3.

[12] APF of 20 assigned based on UK HSE guidance available at https://www.hse.gov.uk/pUbns/priced/hsg53.pdf

9.2.4. WCS 3: Automated process (PROC 1)

This scenario covers the automated melting, dosing and mixing steps in the machine. There are LEV points above the machines and separate LEV arms that are used during tapping, calibrating, or casting liquid polyurethane from the machine.

The automated process is done in a [redacted] casting machine. Each component has a separate tank [redacted]. While filling these tanks LEV is in place, MOCA enters the machine tank as a liquid from the MOCA feeding unit (Glovebox and MOCA Melter). Reaction ratios for the components are entered in the control unit in this casting machine. Once casting operations start, the raw materials (prepolymer and chain extender (MOCA)) will be transferred via gear pump to the mixing head. Once the reaction mixture is past the mixing head, the liquid polyurethane flows into a casting hose (with the requested output (kg/min)).

As all steps in the casting machine are automated, there is no potential for operator exposure during this step in the manufacturing process.

9.2.4.1. Conditions of use

Inhalation	**Method**
Product (article) characteristics	Qualitative
• Substance as such. Concentration of MOCA: 100 % melting and storage, decreasing to minute in the mixing chamber as it reacts with the pre-polymer to yield liquid polyurethane	
Technical and organisational conditions and measures	
• Containment: Closed system (minimal contact during routine operations)	
• Room ventilation: Mechanical ventilation giving at least 1 ACH	
• Local exhaust ventilation: yes	
• Occupational Health and Safety Management System: Advanced	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No	
• Face/eye protection: Yes	
Other conditions affecting workers exposure	
• Place of use: indoors	
• Process temperature: [redacted] [90-140] °C	
* Process is fully automated and contained. No potential for worker exposure	

9.2.4.2. Exposure and risks for workers

Conclusion on risk characterisation:

There is no potential for exposure. The qualitatively determined exposure estimate of 0 µg MOCA/m³ is used as the basis for risk characterisation.

9.2.5. WCS 4: Semi-automated process (PROC 5)

This scenario covers the transfer of liquid MOCA from the storage tank in the machine to a smaller vessel and its mixing in a reaction vessel with the other reactants to yield liquid polyurethane.

[redacted]

The operator doing the tapping and mixing step wears safety shoes, work clothes (with long sleeves), PE apron and sleeves, nitrile gloves, heat resistant gloves, half-face RPE equipped with ABE1P3 filters and safety glasses.

The semi-automated process accounts for [0-20 %] [redacted] of production. 1 operator does this task and the time spent per week is ca. 14 mins. The conditions of use from the transfer of liquid MOCA to vessels (4a) and the mixing of MOCA with other reactants (4b) are considered in the exposure assessment. MOCA reacts with the pre-polymer very quickly and the concentration in the reaction vessel will decrease to minute.

9.2.5.1. Conditions of use

Inhalation: 4a. Transfer of MOCA	**Method**
Substance emission potential	ART 1.5
• Product Type: Liquids	
• Process temperature: Hot	
• Vapor pressure: 0.007 Pa	
• Liquid weight fraction: Pure Material (100 %)	
•Viscosity: Medium viscosity (like oil) *Molten MOCA has viscosity close to oil.*	
Activity emission potential	
• Duration & frequency of activity: 4 mins per week	
• Situation: Falling liquids	
• Activity class: Transfer of liquid products with flow of 1-10 l/minute	
• Containment level: Handling that reduces contact between product and adjacent air	
• Loading type: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (note that the transfer is via a small opening to a small reaction vessel)	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	
Dispersion	
• Work area: Indoors	
• Room size: small workrooms	
Technical and organisational conditions and measures	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
• Primary Localised Controls: Other enclosing hoods (90.00 % reduction)	
• Localised secondary control: No localized controls (0.00 % reduction)	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Occupational Health and Safety Management System: Advanced	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Inhalation: 4b. Mixing MOCA with other reactants	**Method**
Substance emission potential	ART 1.5
• Product Type: Liquids	
• Process temperature: Hot	
• Vapor pressure: 0.007 Pa	
• Liquid weight fraction: minute	
•Viscosity: Medium viscosity (like oil) *Molten MOCA has viscosity close to oil.*	
Activity emission potential	
• Duration & frequency of activity: 10 mins per week	
• Situation: Open surface 0.1 – 0.3 m^2	
• Activity class: Activities with agitated surfaces	
• Containment level: Open	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	
Dispersion	
• Work area: Indoors	
• Room size: Small	
Technical and organisational conditions and measures	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
• Primary Localised Controls: Other enclosing hoods (90.00 % reduction) *Mixing is conducted on the lab bench under LEV*	
• Localised secondary control: No localized controls (0.00 % reduction)	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Occupational Health and Safety Management System: Advanced	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 2012, effectiveness inhalation: 95 % giving a correction of 0.05	

Dermal: 4a Transfer of MOCA	**Method**
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	
• Frequency of skin contact with the contaminant occurs: Rare contact	
• Kind of skin contact with the contaminant occurs: Light contact	
• Product type: Liquid	
• Significant aerosol or splashes formation: No	
• Level of automation: Manual task	
• Rate of use: 1 l/min	
• Percentile: 75th	
• Cumulative duration of the scenario during a shift: 4 minutes weekly	
• Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 % - Frequency 4 mins per week	

Dermal: 4b Mixing MOCA with other reactants	**Method**
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	

• Frequency of skin contact with the contaminant occurs: Rare contact
• Kind of skin contact with the contaminant occurs: Light contact
• Product type: Liquid
• Significant aerosol or splashes formation: No
• Level of automation: Manual task
• Rate of use: 1 l/min
• Percentile: 75th
• Cumulative duration of the scenario during a shift: 10 mins per week
• Skin surface potentially exposed: 820 cm^2
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 % - For the assessment the amount of MOCA left in the PU was assumed 0.1 % - Frequency 10 mins per week

9.2.5.2. Exposure and risks for workers

The measured exposure concentrations are reported in Table 17.

Table 17. Exposure concentrations for WCS 4

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (8h TWA, µg/m^3)	Exposure value corrected for RPE* (µg/m^3)	Exposure value corrected for RPE and frequency** (µg/m^3)
WCS 4a	Inhalation	ART 1.5	7.20E-02	3.60E-03	7.20E-04
WCS 4b			4.00E-04	2.00E-05	4.00E-06

*1/20 **1/5

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (µg/70 kg bw/day)	Exposure value corrected for gloves* (µg/ 70 kg bw/day)	Exposure value corrected for other factors** (µg/ 70 kg bw/day)
WCS 4a	Dermal	Riskoderm	178.57	8.93	1.79
WCS 4b			447.14	22.36	4.47E-03

*1/20 **1/5 (frequency), **WCS4b: 1/1000 (MOCA concentration 0.1%)

Conclusion on risk characterisation:

The modelled exposure values from the inhalation and dermal routes were 7.2E-04 µg/m^3 and 1.79 µg/70 kg bw/day respectively giving excess lifetime risk values 6.99E-09 and 6.03E-05 respectively. This gives a combined excess lifetime cancer risk 6.03E-05. As noted in the Chapter 9.0, biomonitoring data was used as the basis for risk characterisation as it covers all routes of exposure. The risk characterisation from biomonitoring data is summarised in Chapter 9.3.

9.2.6. WCS 5: Transfer of liquid polyurethane to moulds (PROC 4)

This scenario covers the tasks associated with transfer of liquid polyurethane made via the automated and semi-automated processes. [redacted] Note the semi-automated process only applies to [redacted] products and is strongly size-dependent. It accounts for ca. [0-20 %] [redacted] of production.

The [redacted] moulds remains in the oven for PU curing. The oven has exhaust ventilation. A flexible LEV arm is positioned above moulds filled outside the oven.

In total 3 workers do this task. 2 operators per shift do the transfer of polyurethane and ca. 2-5 times per shift each. The average time for casting, when taking into account the annual MOCA consumption and machine output, takes 16 minutes/day (80 kg PU/day) with two operators. Dependent on the items to be casted these times could differ and 20 minutes of casting per operator is an absolute maximum. The operators wear safety shoes, work clothes (with long sleeves), PE apron and sleeves, nitrile gloves, heat resistant gloves, half-face RPE equipped with ABE1P3 filters and safety glasses.

9.2.6.1. Conditions of use

Inhalation	Method
Substance emission potential	ART 1.5
• Substance product type: liquids	
• Process temperature : hot	
Vapour pressure: 0.007 Pa	
• Liquid weight fraction: Minute (0.01-0.1 %) *MOCA has reacted with the pre-polymer and the liquid polyurethane contains minute amounts of MOCA*	
Viscosity: Polyurethane has a viscosity close to oil	
Activity emission potential	
• Duration of activity & frequency: ca. 20 mins per day	
• Activity class: Falling liquids	
• Situation: Transfer of liquid product with flow of 1 – 10 l/minute	
• Containment level: Handling that reduces contact between product and adjacent air Casting to molds that have small opening.	
•Loading type: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely *Closest setting in the model for pouring liquid PU to molds, however minimal splashing is expected due to high viscosity of liquid PU.*	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	
Dispersion	
• Work area: Indoors	
• Room size: > 3000 m^3	
Technical and organisational conditions and measures	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
• Primary: Movable capturing hood (ART parameter: 50.00 % reduction	
• Secondary: No localized controls (0.0 % reduction)	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Occupational Health and Safety Management System: Advanced	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Dermal	Method
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	
• Frequency of skin contact with the contaminant occurs: Rare contact	
• Kind of skin contact with the contaminant occurs: Light contact	
• Product type: Liquid	
• Significant aerosol or splashes formation: No	
• Level of automation: Automated or semi-automated	
• Rate of use: 10 l/min	
• Percentile: 75th	
• Cumulative duration of the scenario during a shift: 20 minutes	
• Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 % - For the assessment the amount of MOCA left in PU mix was assumed 0.1 %	

9.2.6.2. Exposure and risks for workers

The modelled exposure concentrations are reported in Table 18.

Table 18. Exposure concentrations for WCS 5

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (8h TWA, µg/m^3)	Exposure value corrected for PPE* (µg/m^3)	Exposure value corrected for PPE and frequency (µg/m^3)
WCS 5	Inhalation	ART 1.5	3.00E-04	1.50E-05	-

*1/20

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (µg/70 kg bw/day)	Exposure value corrected for gloves* (µg/70 kg bw/day)	Exposure value corrected for other factors** (µg/70 kg bw/day)
WCS 5	Dermal	Riskoderm	1384.29	69.21	6.9E-02

*1/20**1/1000 (MOCA concentration 0.1%)

Conclusion on risk characterisation:

The modelled exposure values from the inhalation and dermal routes were 1.50E-05 µg/m^3 and 6.9E-02 µg/ 70 kg bw/day respectively giving excess lifetime risk values of 1.45E-10 and 2.34E-06 respectively. This gives a combined excess lifetime cancer risk 2.34E-06. As noted in the Chapter 9.0, biomonitoring data was used as the basis for risk characterisation as it covers all routes of exposure. The risk characterisation from biomonitoring data is summarised in Chapter 9.3.

9.2.7. WCS 6: Maintenance & cleaning (PROC 28)

This covers maintenance and cleaning tasks where there is potential for exposure to MOCA. The cleaning and maintenance of work areas is performed regularly by LUC UK operators. Maintenance of the ventilation system is done by external contractors from a specialist service provider (typically 2 contractors). The contractors are trained on the work and safety procedures. Other maintenance is done by LUC operators.

Vacuum cleaners fitted with HEPA filters are used to clean solid spills and wipes are used to clean worktables, weigh stations areas, [redacted] and moulds. The table are then cleaned with BioSAFE[13]. All contaminated waste is collected in a separate waste stream for disposal by incineration.

The cleaning of the machine is done regularly, and the following elements are cleaned and checked:

- On daily base: mixing head and filters
- On weekly base: seals and tanks
- On monthly base: oil level and pressed air

The cleaning of the MOCA Feeding Unit is done regularly, and the following elements are cleaned and checked:

- On daily base: waste bag check/change
- On weekly base: clean window glovebox
- On monthly base: level probes check and external filter change glovebox
- Once per 2 months: internal filter change glovebox
- Half-yearly base: Change gloves of glovebox, filter change feeding unit, heater oil change and valve seal change.

The ovens are cleaned and checked:

- Every 6 months: Ventilation, relays, maximum temperature safety check
- On yearly base: Shelf wheels

Local exhaust ventilation (LEVs) is checked by an external company.

During these cleaning activities, in-house operators wear safety shoes, safety goggles, half face respiratory masks equipped with A1B1E1 and attachable P3 filters, chemical resistant gloves, sleeves and apron. Disposal coveralls and a full face mask may be worn for some tasks.

The estimated time spent per operator on maintenance & cleaning tasks in a typical year is given in the table below.

Table 19. Person hours per year spent on maintenance and cleaning tasks

Type of worker	Number of workers	Total person-time/year
Internal (Group 1)	3	Ca. 4800 minutes
Service provider (Group 2)	2	960 minutes

Internal (Group 1):

- WCS 6a (maintenance heavy contamination – glovebox, LEV, machines): 6 minutes per operator day with 1 operator responsible for these tasks
- WCS 6b (maintenance low contamination – work surfaces, ovens, glassware): 7 minutes per operator / day with 2 operators responsible for these tasks

Service provider (Group 2):

- WCS 6a: 16 hours includes MOCA related maintenance/ inspections. It is done by one external company that does these checks (LEV, air measurements) at the UK facility. Two operators do the tasks in one day.

Most of the tasks involved the handling of contaminated objects and the exposure assessment took the conditions of use for handling contaminated objects. Two sub-scenarios were considered as some tasks will high levels of MOCA contamination (e.g. cleaning and maintenance of the interior of the glovebox, machine and LEV) and others will have

[13] Com position of BioSAFE: 3-methoxy-3-methyl-1-butanol (CAS no. 56539-66-3) ≥10 - <25% (w/w); Sodium carbonate (CAS no. 497-19-8) ≥1 - <2 5% (w/w); Alcohols C12-14 ethoxylated (CAS no. 68439-50-9) <1% (w/w). Used as a 10% dilution (with water)

a low level (e.g. cleaning work surfaces, floors, curing ovens) as [65-100 %] of MOCA used on site is contained in the machine and for the remaining [0-20 %] contamination comes from spills and glassware.

9.2.7.1. Conditions of use

Inhalation 6a: Maintenance (heavy contamination – glovebox, LEV, machines)	**Method**
• Product Type: Powders, granules or pelletised material	ART 1.5
• Dustiness: Granules, flakes or pellets	
• Moisture Content: Dry product (< 5 % moisture content)	
• Powder Weight Fraction: Pure Material	
Activity emission potential	
• Duration & frequency of activity: 6 mins/day Group 1; 8h per year (Group 2)	
• Activity class: Handling of contaminated solid objects or paste	
• Situation: Handling of objects with visible contamination (object covered with fugitive dust from surrounding dusty activities) *Example: Cleaning valves / machinery / equipment with wipe*	
• Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner. *Example: Careful cleaning of surfaces*	
• Containment level: Open process	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	
Dispersion	
• Work area: Indoors	
• Room size: > 3000 m3	
Technical and organisational conditions and measures	
• Primary Localised Controls: No localized controls (0.00 % reduction)	
• Localised secondary control: No localized controls (0.00 % reduction)	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Inhalation 6b: Maintenance (low contamination – work surfaces, ovens, glassware)	**Method**
• Product Type: Powders, granules or pelletised material	ART 1.5
• Dustiness: Granules, flakes or pellets	
• Moisture Content: Dry product (< 5 % moisture content)	
• Powder Weight Fraction: Pure Material	
Activity emission potential	
• Duration & frequency of activity: 7 mins per day (Group 1)	
• Activity class: Handling of contaminated solid objects or paste	
• Situation: Handling of objects with visible contamination Handling of slightly contaminated (layers of less than few grams) objects *Example: Cleaning valves / machinery / equipment with wipe*	
• Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner. *Example: Careful cleaning of surfaces*	
• Containment level: Open process	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	

Inhalation 6b: Maintenance (low contamination – work surfaces, ovens, glassware)	Method
Dispersion	
• Work area: Indoors	
• Room size: > 3000 m3	
Technical and organisational conditions and measures	
• Primary Localised Controls: No localized controls (0.00 % reduction)	
• Localised secondary control: No localized controls (0.00 % reduction)	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Dermal 6a: Maintenance (heavy contamination – glovebox, LEV, machines)	Method
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	
• Frequency of skin contact with the contaminant occurs: Rare contact	
• Kind of skin contact with the contaminant occurs: Light contact	
• Product type: Low or moderately dusty solid	
• Significant aerosol or splashes formation: No	
• Level of automation: Manual task	
• Rate of use: 1 kg/min	
• Percentile: 75th	
• Cumulative duration of the scenario during a shift: 6 minutes (Group 1), 8h per year (Group 2)	
• Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 %	

Dermal 6b: Maintenance (low contamination – work surfaces, ovens, glassware)	Method
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	
• Frequency of skin contact with the contaminant occurs: Rare contact	
• Kind of skin contact with the contaminant occurs: Light contact	
• Product type: Low or moderately dusty solid	
• Significant aerosol or splashes formation: No	
• Level of automation: Manual task	
• Rate of use: 0.1 kg/min	
• Percentile: 75th	
• Cumulative duration of the scenario during a shift: 7 minutes (Group 1)	
• Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 %	

9.2.7.2. Exposure and risks for workers

The measured and modelled exposure concentrations are reported in Table 20.

Table 20. Exposure concentrations for WCS 6

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (8h TWA, µg/m³)	Exposure value corrected for PPE* (µg/m³)	Exposure value corrected for PPE and frequency* (µg/m³)
WCS 6a (G1)	Inhalation	ART	2.10E+00	1.05E-01	-
WCS 6a (G2)			7.20E-01	3.60E-02	-
WCS 6b			2.50E-01	1.25E-02	-

*1/20

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (µg/70 kg bw/day)	Exposure value corrected for gloves* (µg/ 70 kg bw/day)	Exposure value corrected for other factors (µg/70 kg bw/day)
WCS 6a (G1)	Dermal	Riskoderm	9.21	4.6E-01	-
WCS 6a (G2)			3.07	1.54E-01	-
WCS 6b			1.26	6.3E-02	-

*1/20

Conclusion on risk characterisation:

The modelled exposure values for Group1 from the inhalation and dermal routes were 1.18E-01 µg/m³ and 5.24E-01 µg/70 kg bw/day respectively giving excess lifetime risk values of 1.13E-06 and 1.770E-05 respectively. This gives a combined excess lifetime cancer risk 1.88E-05. The modelled exposure values for Group 2 from the inhalation and dermal routes were 3.60E-02 µg/m³ and 0.154 µg/70 kg bw/day giving excess risk value of 3.47E-07 and 5.191E-06 respectively. This gives a combined risk value of 5.54E-06. As noted in the Chapter 9.0, biomonitoring data was used as the basis for risk characterisation as it covers all routes of exposure. The risk characterisation from biomonitoring data is summarised in Chapter 9.3.

9.2.8. WCS 7: Waste management (PROC 8b)

This covers waste handling tasks where there is potential for exposure to MOCA.

All MOCA containing waste is collected for disposal by licenced waste contractors. MOCA waste produced on site includes of empty MOCA plastic inset bags, and contaminated PPE (e.g. gloves, overalls) that have been in contact with solid MOCA. Waste is collected to dedicated containers with appropriate markings and classified prior to final disposal with EWC-codes.

2 LUC UK operators in total have waste handling tasks. Each operator spends ca. 2 mins per day handling waste streams and they wear safety shoes, work clothes (with long sleeves), nitrile gloves and a half-face RPE equipped with ABE1P3 filters and safety glasses.

The conditions of use for handling contaminated objects were used in the exposure assessment.

Figure 7. Photos of waste collection for MOCA inlay bags and MOCA containing waste streams

9.2.8.1. Conditions of use

Inhalation	Method
• Product Type: Powders, granules or pelletised material	ART 1.5
• Dustiness: Granules, flakes or pellets	
• Moisture content: Dry product (< 5 % moisture content)	
• Powder Weight Fraction: Pure Material	
Activity emission potential	
• Duration & frequency: 2 mins per day	
• Activity class: Handling of contaminated solid objects or paste	
• Situation: Handling of slightly contaminated (layers of less than few grams) objects	
• Handling: Careful handling	
Surface contamination	
• Process fully enclosed: No	
• Effective housekeeping practices in place: Yes	

Inhalation	Method
Dispersion	
• Work area: Indoors	
• Room size: > 3000 m^3	
Technical and organisational conditions and measures	
• Primary Localised Controls: No localized controls (0.00 % reduction)	
• Localised secondary control: No localized controls (0.00 % reduction)	
• Ventilation rate: Mechanical ventilation giving at least 1 ACH	
• Secondary emission source: No	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Occupational Health and Safety Management System: Advanced	
• Face/eye protection: Yes	
• Respiratory protection: half face mask with P3 filter, APF 20[12], effectiveness inhalation: 95 % giving a correction of 0.05	

Dermal	Method
• Filling, mixing or loading	Riskofderm
• Quality of the ventilation: Normal or good ventilation	
• Frequency of skin contact with the contaminant occurs: Rare contact	
• Kind of skin contact with the contaminant occurs: Light contact	
• Product type: Low or moderately dusty solid	
• Significant aerosol or splashes formation: No	
• Level of automation: Manual task	
• Rate of use: 0.1 kg/min	
• Percentile: 75th	
• Cumulative duration of the scenario during a shift: 2 minutes	
• Skin surface potentially exposed: 820 cm^2	
Additional corrections applied for calculating the final result: - Body weight of 70 kg was used to calculate exposure per body weight - Gloves with dermal effectiveness of 95 %	

9.2.8.2. Exposure and risks for workers

The modelled exposure concentrations are reported in Table 21.

Table 21. Exposure concentrations for WCS 7

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (8h TWA, µg/m^3)	Exposure value corrected for PPE* (µg/m^3)	Exposure value corrected for PPE and frequency (µg/m^3)
WCS 7	Inhalation	ART 1.5	7.20E-02	3.60E-03	-

*1/20

Contributing Scenario	Route of exposure	Method of assessment	Exposure value (µg/kg bw/day)	Exposure value corrected for gloves* (µg/kg bw/day)	Exposure value corrected for other factors (µg/kg bw/day)
WCS 7	Dermal	Riskoderm	3.6E-01	1.8E-02	-

*1/20

Conclusion on risk characterisation:

The modelled exposure values from the inhalation and dermal routes were 3.6E-03 μg/m^3 and 1.8E-02 μg/kg bw/day respectively giving excess lifetime risk values of 3.47E-08 and 6.04E-07 respectively. This gives a combined excess lifetime cancer risk 6.38E-07. As noted in the Chapter 9.0, biomonitoring data was used as the basis for risk characterisation as it covers all routes of exposure. The risk characterisation from biomonitoring data is summarised in Chapter 9.3.

9.3. Summary

The exposure estimates and risk characterisation values for workers and humans via the environment discussed in Chapter 9.2 are summarized. The values taken forward for assessment for each of the WCS for exposure via the inhalation and dermal routes are summarised in Table 22 and Table 23. There is no exposure to operators for WCS 1 and WCS 3.

Table 22. Summary of exposure concentrations per WCS and the excess lifetime lung cancer risk including information on duration, frequency and RPE usage workers (inhalation route)

WCS	# workers	Method of assessment	Duration & frequency	8h TWA exposure value	Exposure value corrected for RPE (µg/m³)	Exposure value corrected for RPE and frequency (µg/m³)	Exposure value used in the assessment (µg/m³)	Excess risk value
WCS 2	G1 (2)	ART	1 min/2 weeks	3.40E-03	1.70E-04	1.70E-05	1.70E-05	1.64E-10
WCS 4a	G1 (1)	ART	4 mins/week	7.20E-02	3.60E-03	7.20E-04	7.20E-04	6.95E-09
WCS 4b	G1 (1)	ART	10 mins per week	4.00E-04	2.00E-05	4.00E-06	4.00E-06	3.86E-11
WCS 5	G1 (3)	ART	20 mins/day	3.00E-04	1.50E-05		1.50E-05	1.45E-10
WCS 6a	G1 (1)	ART	6 mins/day	2.10E+00	1.05E-01		1.05E-01	1.01E-06
WCS 6a	G2 (2)	ART	2 mins/day	7.20E-01	3.60E-02		3.60E-02	3.47E-07
WCS 6b	G1 (2)	ART	7 mins/day	2.50E-01	1.25E-02		1.25E-02	1.21E-07
WCS 7	G1 (2)	ART	2 mins/day	7.20E-02	3.60E-03		3.60E-03	3.47E-08

Table 23. Summary of exposure concentrations per WCS and the excess lifetime lung cancer risk including information on duration, frequency and RPE usage workers (dermal route)

WCS	# workers	Method of assessment	Duration & frequency	Exposure value (µg/kg bw/day)	Exposure value corrected for 70 kg body weight (µg/70 kg bw/day)	Exposure value corrected for other factors (µg/70 kg bw/day)	Excess risk value
WCS 2	G1 (2)	Riskofderm	1 min/2 weeks	7.78E+03	1.11E+02	5.56E-04	1.878E-08
WCS 4a	G1 (1)	Riskofderm	4 mins/week	1.25E+04	1.79E+02	1.79E+00	6.036E-05
WCS 4b	G1 (1)	Riskofderm	10 mins per week	3.13E+04	4.47E+02	4.47E-03	1.511E-07
WCS 5	G1 (3)	Riskofderm	20 mins/day	9.69E+04	1.38E+03	6.92E-02	2.339E-06
WCS 6a	G1 (1)	Riskofderm	6 mins/day	6.45E+02	9.21E+00	4.61E-01	1.557E-05
WCS 6a	G2 (2)	Riskofderm	2 mins/day	2.15E+02	3.07E+00	1.54E-01	5.191E-06
WCS 6b	G1 (2)	Riskofderm	7 mins/day	8.80E+01	1.26E+00	6.29E-02	2.125E-06
WCS 7	G1 (2)	Riskofderm	2 mins/day	2.50E+01	3.57E-01	1.79E-02	6.036E-07

As outlined in Chapter 9.0, biomonitoring measures overall exposure by all routes of exposure (inhalation, dermal, oral). The ECHA Risk Assessment Committee estimated cancer risks for different urinary MOCA levels measured as total urinary MOCA in samples collected at the end of the work-shift at the end of a working week. Values < 0.5 µmol MOCA/mol creatinine are considered to be the reference values for a non-exposed population and are derived from the LoD of modern analytical methods. 5 µmol MOCA/mol creatinine is the limit value for compliance with the bOELV. The current guidance value in the UK is 15 µmol MOCA/mol creatinine. The cancer risks for these limits are given in RAC/32/2015/10 rev 1;

- *5 µmol MOCA/mol creatinine in a Friday afternoon sample (corresponding to a daily dose of 17 µg) corresponds to a risk of 1.64E-05*
- *0.5 µmol MOCA/mol creatinine (detection limit of current analytical techniques) corresponds to cancer risk of 1.64E-06*

All urine samples at the LUC UK site gave values below the LoD and therefore this value is used for quantifying the excess risk value.

Table 24. Biomonitoring value and excess lifetime cancer risk

WCS	Urinary value for MOCA	Cancer risk type	Excess lifetime cancer risk**
1-7	< 0.5 µmol MOCA/mol creatinine	Lung	1.64E-06

Table 25 compiles the exposure concentrations by the 2 routes considered in the assessment of exposure to humans via the environment for local populations.

Table 25. Summary of the exposure from the environmental contributing scenario local populations

Humans via the environment – route of exposure	Exposure concentration	Cancer risk type	Excess lifetime cancer risk**
Inhalation	1.45E-07	Lung	7.87E-09
Oral intake	1.63E-07	Lung	1.54E-08

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health (related to combined, shift-long exposure)

10.1.1. Workers

The operators doing the tasks described in the WCSs can be grouped into the 2 groups given in Table 26. Group 1 refers to the 4 LUC UK operators bath and Group 2 refers 2 maintenance workers (external contractors).

Table 26. Summary of combined excess risk values by different groups of workers (modelled exposure values via the inhalation & dermal routes)

Worker groups	Number of workers	WCS	Excess risk dermal	Excess risk inhalation	Combined excess risk
Group 1	4	2, 3, 4, 5, 6a, 6b, 7	8.12E-05	1.18E-06	8.23E-05
Group 2	2	6b	5.19E-06	3.47E-07	5.54E-06

The highest combined excess risk value coming from one shift to one operator in Group 1 is given in Table 27.

Table 27. Combined risk characterisation (modelled exposure via inhalation & dermal routes)

Contributing scenario	Route of exposure	Excess risk
WCS 2, 3, 4, 5, 6a, 6b, 7	Inhalation & Dermal	8.23E-05

As outlined in Chapter 9.3, biomonitoring data was used to estimate the overall occupational exposure to MOCA by all routes of exposure. This value is more reliable than the modelled data as it covers all routes of exposure.

Table 28. Combined exposure and risk characterisation for workers

Contributing Scenarios	Route of exposure	Total number of workers taken to be directly exposed	Urinary value for MOCA	Excess risk value
WCS 1-7	All	4 + 2 of external operators	< 0.5 µmol MOCA/mol creatinine	< 1.64E-06

10.1.2. Consumers

Not relevant as there is no consumer use.

10.2. Environment (combined for all emission sources)

As MOCA is not listed in REACH Annex XIV due to environmental effects, no environmental exposure assessment is performed here.

Man via environment

Exposure of humans via the environment and associated risks are discussed and presented in Chapter 9.1.1. above (local and regional scale) and summarised in Table 29 respectively.

Table 29. Summary of the exposure from the environmental contributing scenario regional populations

Humans vis the environment – route of exposure	Exposure concentration	Cancer risk type	Excess lifetime cancer risk*
Inhalation	9.01E-12	Lung	4.89E-13
Oral intake	2.72E-11	Lung	2.57E-12

* 70 years

10.2.1. All uses (regional scale)

Not relevant as no environmental assessment is performed

REFERENCES

European Chemicals Agency:

Exchange network on exposure scenarios (ENES) report "*Mapping of the Conditions of use (input parameters) of the different tools for workers assessment*" December 2020 available at https://echa.europa.eu/documents/10162/2138220/harmnised_conditions_of+use_for_workers_en.pdf/3b327551-19b3-5d56-8b13-a608695d4419?t=1607957710837

LUC application for authorisation for 2 uses of MOCA under EU REACH; use 1 ECHA ID 0225-01 and Use 2 ECHA ID 0225-02 available on the ECHA website at https://echa.europa.eu/applications-for-authorisation-previous-consultations

UK HSE:

Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply; Available at https://www.hse.gov.uk/pubns/priced/l5.pdf

UK HSE services relating to Biological Monitoring Guidance Values available at https://www.hsl.gov.uk/online-ordering/analytical-services-and-assays/biological-monitoring/bm-guidance-values

UK HSE Guidance for preventing skin contact during the removal of gloves available at the UK HSE website at https://www.hse.gov.uk/pubns/msa21.htm

HSE Guidance on correct removal of gloves available at https://www.hse.gov.uk/skin/posters/glovesreuse.pdf

Respiratory protective equipment at work, A practical guide; HSG53 (Fourth edition, published 2013). Health and Safety Executive, ISBN 978 0 7176 6454 2 available at https://www hse.gov.uk/pUbns/priced/hsg53.pdf

2014 BE SAFE WITH MbOCA leaflet prepared by the UK HSE and BRPPA available at https://brppa.co.uk/wp-content/uploads/2014/03/BRPPA-HSE-Safe-Use-Of-MbOCA.pdf

European Commission:

COMMISSION REGULATION (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2020.252.01.0024.01.ENG

DIRECTIVE (EU) 2019/130 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0130&from=EN

Websites:

European Diisocyanate and Polyol Producers Association website https://www.isopa.org/

GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs) database available at https://limitvalue.ifa.dguv.de/

APPENDICES

Appendix I. Compiled monitoring data

Table 30 lists the standards methods used for the occupations air monitoring programs in place.

Table 30. Summary of the methods used for occupational air monitoring

Service provider	accredited external service provider
Method of sampling & analysis	OSHA 71
Limit Of Detection / Limit Of Quantification	1 µg
Location of sampling	Personal: Sampling with selector in the employee's respiratory area outside of personal PPE.

Table 31 compiles the short terms personal monitoring data. The monitoring covered specific tasks done in the worker contributing scenarios.

Table 31. Summary of personal monitoring data

No.	Date	Results [µg/m³]	tasks done by operator during monitoring period	RPE	Duration [min]	Sampling volume [liters]	Reference to WCS
1	27.10.2020	< 2.5*	normal range of duties including loading MOCA to the machine without a glovebox*	yes	400	400	2-7
2	5.7.2017	< 4.3*	normal range of duties including loading MOCA to the machine without a glovebox*	yes	233	233	2-7
3	7.7.2016	< 3*	normal range of duties including loading MOCA to the machine without a glovebox*	yes	337	337	2-7

ND = not detected *glovebox installed in Q2 2021

Table 32 summaries the data from the biomonitoring campaigns. The color codes and % values refer to the value as a percentage of the biomonitoring guidance value (BMGV). Green is for values < 10 % BMGV, amber for values 10.50 % of the BMGV and red is for values > 50 % of the BMGV. From the 2020 campaign, all values are green.

Table 32. Summary of biomonitoring campaigns

Function/Job	Test result MbOCA [µmol/mol creatinine]					
[-]	Sep-12		Dec-13		Mar-20	
Logistics	ND	-	ND	-	ND	-
Turning	-	-	ND	-	ND	-
Blasting*	-	-	0.4	2.7%	-	-
Lab*	ND	-	ND	-	ND	-
Machine/casting*	2.8	18.7 %	3.8	25.3 %	-	-
Machine/casting*	ND	-	0.7	4.7%	-	-
Turning	-	-	ND	-	ND	-
Turning	-	-	ND	-	-	-

Bonding	-	-	ND	-	-	-
Casting*	-	-	1.2	8.0%	-	-
Blasting	-	-	-	-	ND	-
Machine/casting	-	-	-	-	ND	-
Machine/casting	-	-	-	-	ND	-
Casting/Lab	-	-	-	-	ND	-
Turning	-	-	-	-	ND	-

*** Operators have left LUC UK for other employment**

Details for the external labs who performed the analysis and the limits of detection (LoD) of the analysis methods are given below.

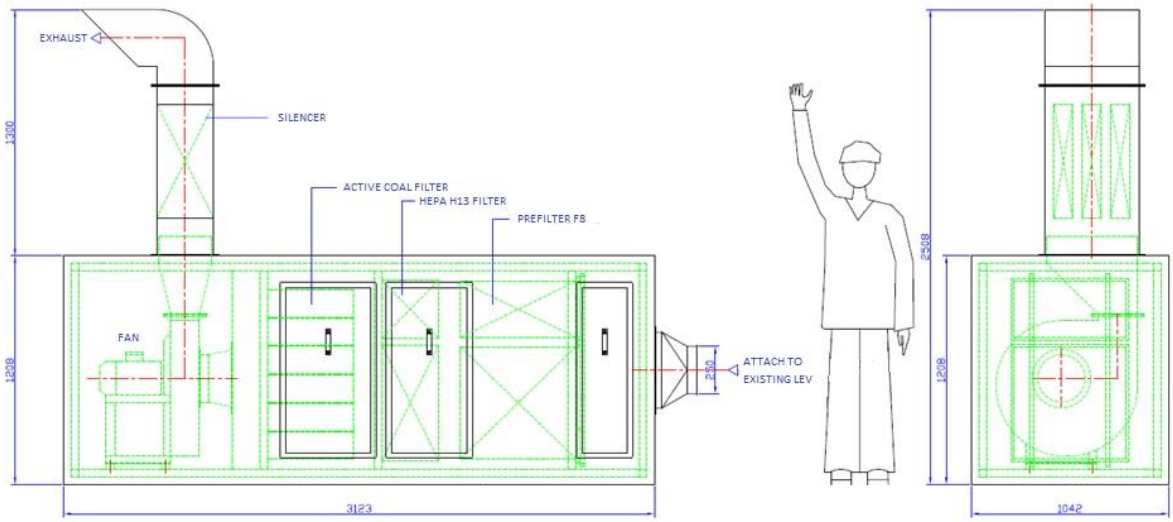
	Sep-12	**Dec-13**	**Mar-20**
Analyselab	Health & Safety Laboratory	Health & Safety Laboratory	Marchwood Scientific Services
LoD	5 nmol/l	5 nmol/l	0.42 µmol/mmol

Appendix II. Air filters

The LUC group is installing filtration systems in the exhaust ventilation system. A schematic is given in Figure 8. Air removed by LEV units moves through a filter box (see below). This filter box is divided in three “phases”. Phase 1 contains a F8 class prefilter that has an average efficiency (Em) for 0.4 micron particles of $90 \leq Em \leq 95$. Phase 2 is equipped with a HEPA H13 filter. HEPA H13: pass up 0.05 % of 0.1 micron particles per liter of air. Phase 3, which is the last filtering step is an active coal filter, that binds the vapours (VOC’s and other gaseous pollutants) passing through the first two filters in the filter box.

Installation was delayed due to the Covid pandemic and is now scheduled for delivery in week 31 and operational by week 40.

Figure 8. Schematic of the exhaust ventilation filtration system



Appendix III. Fit-test for RPE

FIT-TEST FACE MASK

LUC Group
High Tech in Polyurethane

Test Date: .....

Name user: ..... Birth date: .....
Function: ..... Department: .....

The user has been instructed in the correct use of the following face mask and has also performed a fit test:

☐ Type Face Mask: ☐ **Half Face Mask** ☐ **Full Face Mask**
☐ Type of issue: ☐ Subject's ☐ Company pool ☐ Test Piece
☐ Make/Model/Material/Size: .....
☐ Type of filter: .....
☐ PPE/RPE accessory: ☐ No ☐ Yes: .....
☐ In-facepiece spectacles: ☐ No ☐ Yes: .....
☐ Facial hair: ☐ No ☐ Yes: .....
☐ Fit-Test Method
- ☐ Quantitative test: ☐ Fit factor: ..... ☐ Passed ☐ Failed
- ☐ Qualitative test agent: ☐ Agent used: ..... ☐ Passed ☐ Failed
- ☐ Positive pressure fit-test (inhaling): ☐ Passed ☐ Failed
- ☐ Negative pressure fit-test (exhaling): ☐ Passed ☐ Failed

☐ Additional info (test exercises, pass level, etc.): .....

The following documents apply to this fit test and the user declares that they are familiar with and will adhere to the relevant content:

- WI-04-002-GR - Personal Protective Equipment
- WI-04-003-GR - Use Face mask

The user is responsible for the safe performance of the relevant activities, whereby only suitable personal respiratory protection equipment made available by the company will be used. The correct fit should be checked by the user each time before use.

Instructor / Test witness: **User:**
Name: ..... Name: .....
Company: ..... Company: .....
Signature: ..... Signature: .....

In the event of a change of the type of face mask and if the face has changed in such a way that this affects the fit, this test must be repeated again in the presence of a witness on behalf of the employer.

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Appendix IV. ART print outs

ART REPORT – MOCA WCS 2 – 27-May-22

transfer of granules to machine with the glovebox

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	479

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	01-Jan-01

Details for Activity transfer of granules to machine in the glovebox

Emission sources: Near field ✓ Duration (mins): 1

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Powders, granules or pelletised material
Dustiness	Granules, flakes or pellets
Moisture content	Dry product (< 5 % moisture content)
Powder weight fraction	1

Activity emission potential	
Activity class	Falling powders
Situation	Transferring 10 – 100 kg/minute
Handling type	Careful transfer involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.
Drop height	Drop height < 0.5 m
Containment level	Open process

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	Low specification glove box (99.90 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	Mechanical ventilation giving at least 1 ACH

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0000034 mg/m^3.

The inter-quartile confidence interval is 0.0000017 mg/m^3 to 0.000007 mg/m^3.

ART REPORT – MOCA WCS 4**a** – 14-Jun-22

Transfer of hot MOCA from the machine unit to a small container

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	476

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity WCS 4 transfer of hot MOCA

Emission sources: Near field ✓ Duration (mins): 4

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Hot
Vapour pressure	0.007 Pa
Liquid weight fraction	1
Viscosity	Medium

Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	Small workrooms only

Risk Management Measures

Localised controls	
Primary	Fixed capturing hood (90.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.000072 mg/m^3.

The inter-quartile confidence interval is 0.000032 mg/m^3 to 0.00016 mg/m^3.

ART REPORT – MOCA WCS 4b – 23-Jun-22

mixing step - hot MOCA mixed with pre-polymer

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	470

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity WCS 4 transfer of hot MOCA

Emission sources: Near field ✓ Duration (mins): 10

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Hot
Vapour pressure	0.007 Pa
Liquid weight fraction	Minute
Viscosity	Medium
Activity emission potential	
Activity class	Activities with agitated surfaces
Situation	Open surface 0.1 – 0.3 m^2
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Small workrooms only

Risk Management Measures

Localised controls	
Primary	Fixed capturing hood (90.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0000004 mg/m³.

The inter-quartile confidence interval is 0.00000018 mg/m³ to 0.00000092 mg/m³.

ART REPORT – MOCA WCS 5 – 14-Jun-22

transferring liquid PU with minute amounts of unreacted MOCA to moulds

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	460

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity dispensing liquid PU to moulds

Emission sources: Near field ✓ Duration (mins): 20

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Hot
Vapour pressure	0.007 Pa
Liquid weight fraction	Minute
Viscosity	Medium

Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	Movable capturing hood (50.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0000003 mg/m³.

The inter-quartile confidence interval is 0.00000013 mg/m³ to 0.00000069 mg/m³.

ART REPORT – MOCA WCS 6 – 01-Jun-22

maintenance: handling contaminated objects

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	474

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity maintenance tasks

Emission sources: Near field ✓

Far field

Duration (mins): 6

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Powders, granules or pelletised material
Dustiness	Granules, flakes or pellets
Moisture content	Dry product (< 5 % moisture content)
Powder weight fraction	Pure material

Activity emission potential	
Activity class	Handling of contaminated solid objects or paste
Situation	Handling of objects with visible contamination (object covered with fugitive dust from surrounding dusty activities)
Handling type	Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0021 mg/m^3.

The inter-quartile confidence interval is 0.0011 mg/m^3 to 0.0045 mg/m^3.

ART REPORT – MOCA WCS 6 – 01-Jun-22

maintenance: handling contaminated objects

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	478

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity maintenance tasks

Emission sources: Near field ✓ Far field

Duration (mins): 2

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Powders, granules or pelletised material
Dustiness	Granules, flakes or pellets
Moisture content	Dry product (< 5 % moisture content)
Powder weight fraction	Pure material

Activity emission potential	
Activity class	Handling of contaminated solid objects or paste
Situation	Handling of objects with visible contamination (object covered with fugitive dust from surrounding dusty activities)
Handling type	Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.00072 mg/m³.

The inter-quartile confidence interval is 0.00036 mg/m³ to 0.0015 mg/m³.

ART REPORT – MOCA WCS 6b – 01-Jun-22

maintenance: handling contaminated objects - not dusty

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	473

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity maintenance tasks

Emission sources: Near field ✓ Far field

Duration (mins): 7

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Powders, granules or pelletised material
Dustiness	Granules, flakes or pellets
Moisture content	Dry product (< 5 % moisture content)
Powder weight fraction	Pure material

Activity emission potential	
Activity class	Handling of contaminated solid objects or paste
Situation	Handling of slightly contaminated (layers of less than few grams) objects
Handling type	Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.00025 mg/m³.

The inter-quartile confidence interval is 0.00012 mg/m³ to 0.00052 mg/m³.

ART REPORT – MOCA WCS 7 – 14-Jun-22

waste handling

Chemical details	
Chemical	MOCA
CAS No.	101-14-4

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	478

Metadata	
ART version	1.5
Creator	
Date created	27-May-22
Date last edited	27-May-22

Details for Activity maintenance tasks

Emission sources: Near field ✓ Duration (mins): 2

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Powders, granules or pelletised material
Dustiness	Granules, flakes or pellets
Moisture content	Dry product (< 5 % moisture content)
Powder weight fraction	Pure material

Activity emission potential	
Activity class	Handling of contaminated solid objects or paste
Situation	Handling of slightly contaminated (layers of less than few grams) objects
Handling type	Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	1 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.000072 mg/m^3.

The inter-quartile confidence interval is 0.000036 mg/m^3 to 0.00015 mg/m^3.